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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,100	10/31/2003	Martin T. Gerber	P-11668.00	9709

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EXAMINER	
KASZTEJNA, MATTHEW JOHN	
ART UNIT	**PAPER NUMBER**
3739	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,100	GERBER ET AL.	
	Examiner	Art Unit	
	Matthew J. Kasztejna	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6,7,11,13 and 15-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6,7,11,13 and 15-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on November 22, 2005, the current rejections of the claims are *withdrawn*. The following new grounds of rejection are set forth:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "approximately" in claim 1 is a relative term which renders the claim indefinite. The term "approximately" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13, 16-23 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,231,591 to Desai in view of U.S. Patent No. 5,599,294 to Edwards et al. in further view of U.S. Patent No. 5,486,161 to Lax et al.

In regards to claims 13 and 29, Desai discloses a device for delivering a denervating agent to a prostate gland comprising: a shaft 309 for insertion into a urethra in proximity to the prostate gland, a needle 306 within the shaft, the needle defining a lumen, (see Col. 18, Lines 55-60); an actuator 338 to cause the needle to extend through the hole into the prostate gland when the shaft is inserted in proximity to the prostate gland; and a denervating agent delivery assembly 348 to cause the denervating agent to pass through the lumen and into the prostate gland when the shaft is inserted in proximity to the prostate gland and the needle is extended out into the prostate gland (see Col. 17, Lines 18-57) but is silent with respect to the shaft defining a hole on a side of the shaft in proximity to a distal tip of the shaft and wherein a distal end of the needle is extendable through the hole out the side of the shaft out the side of the shaft and into the prostate gland. Edwards et al. teach of an analogous medical probe having stylet ports 40 positioned on the side of the shaft 14 from which a stylet 36 can be extended until it penetrates a target tissue such as the prostate gland (see Fig. 3). It would have been obvious to one skilled in the art at the time the invention was made to position the exit hole on the side of the shaft in the apparatus of Desai in order to provide access to the target tissue at a any number of different angles and positions as taught by Edwards et al. Desai and Edwards et al. disclose an apparatus wherein a slidable portion 338 is responsible for extending and retracting a needle 306 into tissue

but are silent with respect to an actuator wherein the needle is spring-loaded such that the needle is spring biased into the prostate gland. Lax et al. teach of an analogous medical probe having a cutting cannula 84 which is spring-loaded in a retracted position and wherein a release tab 108 is pushed down to move the cannula forward when desired. It would have been obvious to one skilled in the art at the time the invention was made to include a spring-loaded needle in the invention of Desai and Edwards et al. to allow for more efficient and effective actuation of the needle into tissue as taught by Lax et al.

In regards to claim 16, Desai discloses a device for delivering a denervating agent to a prostate gland further comprising an endoscope 304 housed within the shaft and wherein the distal tip comprises substantially transparent material such that the endoscope can view through the distal tip (see Col. 16, Lines 58-65).

In regards to claim 17, Desai discloses a device for delivering a denervating agent to a prostate gland wherein the distal tip of the shaft defines an offset curvature to improve navigation of the shaft through the urethra into proximity to the prostate gland (see Fig. 25).

In regards to claims 18-19, Desai discloses a device for delivering a denervating agent to a prostate gland having an actuator for advancement of the needle into the prostate gland to various depths with actuator being a slide bar 338 (see Col. 20, Lines 1-25).

In regards to claims 20-22, Desai discloses a device for delivering a denervating agent to a prostate gland wherein the denervating agent delivery system

assembly 348 includes a reservoir to hold the denervating agent and a second actuator to cause the denervating agent to flow from the reservoir through the lumen. As can be seen in Fig. 25 the second actuator comprises a plunger as well as a hub and a fluid line for attachment of the reservoir to the needle (see Col. 17, Lines 53-55).

In regards to claims 23 and 25-26, Desai discloses a device for delivering a denervating agent to a prostate gland wherein the denervating agent delivery system assembly 348 includes a first reservoir to hold a substantial amount of the denervating agent and a second reservoir to hold a discrete dose of the denervating agent, wherein the second reservoir refills with another discrete dose of the denervating agent from the first reservoir following actuation of the second actuator (see col. 20, Lines 65-51, and Col. 21, Lines 18-30). Syringe 348 is interpreted to be the first reservoir and the lumen of needle 306 is interpreted to be the second reservoir.

In regards to claim 27, Desai discloses a device for delivering a denervating agent to a prostate gland wherein further comprising a plurality of needles within the shaft, each of the plurality of needles defining a respective lumen, wherein a distal end of a given one of the needles is extendable through the shaft; wherein the actuator causes the plurality of needles to extend through the plurality of holes when the shaft is inserted in proximity to the prostate gland; and wherein the denervating agent delivery system causes the denervating agent to pass through the respective lumens of the plurality of needles into the prostate gland when the shaft is inserted in proximity to the prostate gland and the needles are extended through the holes into the prostate gland (see Col. 32, Line 58 – Col. 22, Line 8) but is silent with respect to a plurality of holes

formed on the side of shaft. Edwards et al. teach of an analogous medical probe having stylet ports 40 positioned on the side of the shaft 14 from which stylets 36 can be extended until it penetrates a target tissue such as the prostate gland (see Fig. 3). It would have been obvious to one skilled in the art at the time the invention was made to position the exit hole on the side of the shaft in the apparatus of Desai in order to provide access to the target tissue at a any number of different angles and positions as taught by Edwards et al.

In regards to claim 28, Desai discloses a device for delivering a denervating agent to a prostate gland wherein the shaft is semi-flexible (see Col. 19, Lines 59-62).

Claims 1, 3-4, 6-7, 11, 15 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,231,591 to Desai in view of U.S. Patent No. 5,599,294 to Edwards et al. in further view of U.S. Patent No. 6,365,164 to Schmidt and "Guidelines for Botox Reconstitution" 1 pg., http://www.botox.com/download/reconstitution.pdf.

In regards to claims 1 and 15, Desai and Edwards et al. disclose a device for delivering a denervating agent to a prostate gland shaft but are silent with respect to the denervating agent including botulinum toxin. Schmidt teaches methods for treating neuronally-mediated urologic and related disorders and more particularly, benign prostatic hyperplasia (BPH), by administering a composition that includes at least one neurotoxic compound. Such a neurotoxin can be botulinum toxin type A (see Col. 4, Lines 3-29). Neurotoxin can be delivered serially (i.e., one time per month, one time per every six months) so that the therapeutic effect can be optimized. Such a dosage

schedule is readily determined by one skilled in the art based on, e.g., patient size and the condition to be treated, and will depend on many factors, including the neurotoxin selected, the condition to be treated, the degree of irritation, and other variables. Schmidt discloses that dosing can be singular or cumulative and can be readily determined by one skilled in the art (see Col. 4, Lines 36-60). Furthermore, as seen in the dilution table of "Guidelines for Botox Reconstitution" the total dosage of 50 to 400 units as recited in claim 1 can be calculated be one of ordinary skill in the art. It would have been obvious to one skilled in the art at the time the invention was made to use a composition including botulinum toxin type A with the device of Desai and Edwards et al. in order to help more effectively treat BPH as taught by Schmidt and shown in the dilution table of "Guidelines for Botox Reconstitution".

In regards to claims 3-4, 6-7 and 11, the apparatus of Desai, Edwards et. al and Schmidt is considered to be inherently capable of performing the recited method claims. Furthermore, Desai discloses a method of localized fluid therapy (see Col. 19, line 57 – Col. 20, Line 51).

In regards to claim 24, Desai and Edwards et al. disclose a device for delivering a denervating agent to a prostate gland shaft but are silent with respect to the first reservoir holding greater then 4mm of botulinum toxin, and the second reservoir holding less than approximately 1 mm of the botulinum toxin. Schmidt teaches methods for treating (BPH), by administering a composition including botulinum toxin type A (see Col. 4, Lines 3-29). Furthermore, Schmidt teaches that one skilled in the art can readily

determine dosing for treatment. Therefore, pending a criticality statement, the reservoirs retaining volumes is a design consideration that is not patentably distinct.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-7, 11, 13 and 15-29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJK MK
1/4/06

BEVERLY M. FLANAGAN
PRIMARY EXAMINER